to be manufactured under an agreement with Paragon Optical, Mesa, AZ, which has authorized Sola/Barnes-Hind to incorporate information contained in its approved premarket approval application and related supplement for the FluoroPerm ™ (paflufocon A) Rigid Gas Permeable Contact Lenses for Daily Wear and FluoroPerm® 60 (paflufocon B) Rigid Gas permeable Contact Lenses for Daily and Extended Wear (Clear and Tinted). FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of December 28, 1990, of the approval of the application.

**DATES:** Petitions for administrative review by May 1, 1991.

**ADDRESSES:** Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, Room 4–62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

David M. Whipple, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 1390 Piccard Drive, Rockville, MD 20850, 301–427–1080.

**SUPPLEMENTARY INFORMATION:** On September 29, 1989, Sola/Barnes-Hind, Sunnyvale, CA 94086–5200, submitted to CDRH a supplemental application for premarket approval of the spherical Fluorocon™ (paflufocon B) Rigid Gas Permeable Contact Lenses for Daily and Extended Wear (Clear and Tinted). The Fluorocon™ (paflufocon B) Rigid Gas Permeable Contact Lenses (Clear and Tinted) are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. The lenses are indicated for the correction of visual acuity in not-aphakic persons with nondiseased eyes who are myopic or hyperoic and may have corneal astigmatism of 4.00 diopters (D) or less that does not interfere with visual acuity. The daily wear lenses range in powers from −20.00 D to +12.00 D and the extended wear lenses range in powers from −20.00 D to +8.00 D. These lenses are to be disinfected using a chemical lens care system. The lenses are available in untinted (clear), blue, or green tints. The tinted lenses contain one or both of the color additives, D&C Green No. 6 and D&C Yellow No. 10, in accordance with the color additive listing provisions of 21 CFR 74.3206 and 74.3710. The application includes authorization from Paragon Optical of Mesa, AZ 85204, to incorporate information contained in its approved premarket approval application and related supplement for the Fluoroperm™ (paflufocon A) Rigid Gas Permeable Contact Lenses for Daily Wear and FluoroPerm® 60 (paflufocon B) Rigid Gas Permeable Contact Lenses for Daily and Extended Wear (Clear and Tinted).

On December 28, 1990, CDRH approved the application by letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact David M. Whipple (HFZ–460), address above. The labeling of the Fluorocon™ (paflufocon B) Rigid Gas Permeable Contact Lenses for Daily and Extended Wear (Clear and Tinted) states that the lens is to be used only with certain solutions for disinfection and other purposes. The restrictive labeling informs new users that they must avoid using certain products, such as solutions intended for use with hard contact lenses only.

### Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act ) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review, to be used, the persons who may participate in the review, the time and place where the review will occur, and othe details.

Petitioners may, at any time on or before (May 1, 1991, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: March 22, 1991.

**Elizabeht D. Jacobson,**

*Acting Director, Center for Devices and Radiological Health.*

[FR Doc. 91–7515 Filed 3–29–91; 8:45 am]

BILLING CODE 4160–01–M

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**[Docket No. 91M–0089]**

## Vision Technologies International; Premarket Approval of Models A21–A and A21–B Ultraviolet-Absorbing Posterior Chamber Intraocular Lenses

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its approval of the application by Vision Technologies International, San Dimas, CA, for premarket approval, under the Medical Device Amendments of 1976, of the Models, A21–A and A21–B Ultraviolet-Absorbing Posterior Chamber Intraocular Lenses (IOL's). The IOL's are to be manufactured under an agreement with Newlensco, Monrovia, CA, which has authorized Vision Technologies International to incorporate information contained in its approved premarket approval application for the Newlensco UV Classic Series™ Posterior Chamber IOL's. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of February 28, 1991, of the approval of the application.

**DATES:** Petitions for administrative review by May 1, 1990.

**ADDRESSES:** Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food

and Drug Administration, rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

Nancy C. Brogdon, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301–427–1212.

**SUPPLEMENTARY INFORMATION:** On August 7, 1990, Vision Technologies International, San Dimas, CA 91773, submitted to CDRH an application for premarket approval of Models A21–A and A21–B Ultraviolet-Absorbing Posterior Chamber IOL's. The lenses are indicated for use in the visual correction of aphakia in patients 60 years of age or older, who are undergoing a primary lens implantation in either the ciliary sulcus or capsular bag, following an extracapsular cataract extraction. The lenses are available in a range of powers from 10 diopters (D) through 30 D in 0.5–D increments. The application includes authorization from Newlensco, Monrovia, CA 91016, to incorporate information contained in its approved premarket approval application for the Newlensco UV Classic Series IOL's.

On February 28, 1991, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact Nancy C. Brogdon (HFZ–460), address above.

**Opportunity for Administrative Review**

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish notice of its decision in the **Federal Register.** If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before May 1, 1991, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m. Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sections 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: March 22, 1991.

**Elizabeth D. Jacobson,**

*Acting Director, Center for Devices and Radiological Health.*

[FR Doc. 91–7516 Filed 3–29–91; 8:45 am]

BILLING CODE 4160–01–M

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**Health Care Financing Administration**

**[BPD–464–FNC]**

**RIN 0938–AD48**

## Medicare Program; Schedule of Limits for Skilled Nursing Facility Inpatient Routine Service Costs

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Final notice with comment period.

**SUMMARY:** This final notice with comment period sets forth an updated schedule of limits on skilled nursing facility inpatient routine service costs for which payment may be made under the Medicare program.

**DATES:** Effective Date: The schedule of limits is effective for cost reporting periods begining on or after October 1, 1986

Comment Date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on May 31, 1991.

**ADDRESSES:** Mail comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–464–FNC, P.O. Box 26676, Baltimore, Maryland 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC.

Room 132, East High Rise Building, 3625 Security Boulevard, Baltimore, Maryland.

Due to staffing and resource limitations, we cannot accept facsimile (FAX) copies of comments.

In commenting, please refer to file code BPD–464–FNC. Comments received timely will be available for public inspection as they are received, beginning approximately three weeks after publication of this document, in Room 309–G of the Department's offices at 200 Independence Avenue SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: 202–245–7890).

**FOR FURTHER INFORMATION CONTACT:**

Robert Kuhl, (301) 966–4597.

**SUPPLEMENTARY INFORMATION:**

### I. Background

Sections 1861(v)(1) and 1888 of the Social Security Act (the Act) authorize the Secretary to set limits on allowable costs incurred by a provider of services for which payment may be made under Medicare. These limits are based on estimates of the costs necessary for the efficient delivery of needed health services. Implementing regulations appear at 42 CFR 413.30. Section 1888 of the Act directs the Secretary to set limits on per diem inpatient routine service costs for hospital-based and freestanding skilled nursing facilities (SNFs) by urban or rural area location.

Under the authority of section 1888 of the Act, we published a final notice on April 1, 1986 (51 FR 11253) announcing a schedule of limits for freestanding and hospital-based SNFs effective for cost reporting periods beginning on or after May 1, 1986.

That final notice contained provision relating to: (1) Limits on adjusted SNF per diem inpatient routine service costs; (2) a "market basket" index developed to reflect changes in the price of goods and services purchased by SNFs; (3) adjustments to the cost limits by an area wage index developed from hospital industry wages; (4) a classification system based on whether the SNF is hospital-based or freestanding and